ASSEMBLY BILL No. 1959

Introduced by Assembly Members Chu, Frommer, Pavley, and Ridley-Thomas

February 12, 2004

An act to amend Section 14977.1 of, and to add Section 22790.1 to, the Government Code, and to amend Section 14105.33 of the Welfare and Institutions Code, relating to health care contracts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1959, as introduced, Chu. Health care.

Existing law authorizes the Department of General Services to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multiple source drugs, authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law, and provides that those contracts are exempt from competitive bid and other acquisition procedures applicable to the state acquisition of goods and services. Existing law requires the State Department of Mental Health, the Department of Corrections, the Department of the Youth Authority, and the State Department of Developmental Services to participate in the program, and authorizes other state, local, and public agency governmental entities to elect to participate in that contracting program.

Existing law, the Public Employees' Medical and Hospital Care Act, authorizes the Board of Administration of the Public Employees' Retirement System to contract with eligible carriers for health benefits plans for employees and annuitants and major medical plans or approve health benefits plans offered by employee organizations.

Existing law authorizes the State Department of Health Services to enter into contracts with manufacturers of single-source and multiple source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and requires the department to maintain a list of those drugs for which contracts have been executed. Existing law also provides that those contracts are exempt from competitive bid and other acquisition procedures applicable to the state acquisition of goods and services.

This bill would authorize the chair and vice chair of specified committees of the Legislature to inspect any of those contracts, and would require the chair and vice chair of those committees to maintain the confidentiality of the contractS or amendments to the contract.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 14977.1 of the Government Code is amended to read:

14977.1. (a) Notwithstanding any other provision of law, the Department of General Services may enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. The department may obtain from those manufacturers and suppliers, discounts, rebates, or refunds based on quantities purchased insofar as permissible under federal law. Contracts entered into pursuant to this chapter may include price discounts, rebates, refunds, or other strategies aimed at managing escalating prescription drug prices.

(b) Contracts under this chapter shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

Notwithstanding any other provision of law, any contract or amendments to the contract subject to this section shall be open to inspection by the chair and vice chair of the following legislative committees, who shall maintain the confidentiality of the contracts and amendments thereto, until the contract or amendments to the contract are open to inspection by the public.

(1) The Assembly Committee on Health.

(2) The Senate Committee on Health and Human Services.

(3) The Assembly Committee on Budget.

(4) The Senate Committee on Budget and Fiscal Review.

SEC. 2. Section 22790.1 is added to the Government Code, to read:

22790.1. All contracts entered into by the board for health benefits for employees and annuitants, including prescribed drug benefits, shall be open to inspection by the chair and vice chair of the following legislative committees, who shall maintain the confidentiality of the contracts and amendments thereto, until the contracts or amendments to the contract are open to inspection by the public:

(a) The Assembly Committee on Health.

(b) The Senate Committee on Health and Human Services.

(c) The Assembly Committee on Budget.

(d) The Senate Committee on Budget and Fiscal Review.

SEC. 3. Section 14105.33 of the Welfare and Institutions Code is amended to read:

14105.33. (a) The department may enter into contracts with manufacturers of single-source and multiple-source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and shall maintain a list of those drugs for which contracts have been executed.

(b) (1) Contracts executed pursuant to this section shall be for the manufacturer's best price, as defined in Section 14105.31, which shall be specified in the contract, and subject to agreed-upon price escalators, as defined in that section. The contracts shall provide for an equalization payment amount, as defined in Section 14105.31, to be remitted to the department quarterly. The department shall submit an invoice to each manufacturer for the equalization payment amount, including supporting utilization data from the department's prescription drug paid claims tapes within 30 days of receipt of the Centers for Medicare and Medicaid Services' file of manufacturer rebate information. In lieu of paying the entire invoiced amount, a manufacturer may contest the invoiced amount pursuant to procedures established by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations by mailing a notice, that shall set forth its grounds for contesting the invoiced amount, to the department within 38 days of the department's mailing of the state invoice and supporting utilization data. For purposes of state

accounting practices only, the contested balance shall not be considered an accounts receivable amount until final resolution of the dispute pursuant to procedures established by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations that results in a finding of an underpayment by the manufacturer. Manufacturers may request, and the department shall timely provide, at cost, Medi-Cal provider level drug utilization data, and other Medi-Cal utilization data necessary to resolve a contested department-invoiced rebate amount.

(2) The department shall provide for an annual audit of utilization data used to calculate the equalization amount to verify the accuracy of that data. The findings of the audit shall be documented in a written audit report to be made available to manufacturers within 90 days of receipt of the report from the auditor. Any manufacturer may receive a copy of the audit report upon written request. Contracts between the department and manufacturers shall provide for any equalization payment adjustments determined necessary pursuant to an audit.

(3) Utilization data used to determine an equalization payment amount shall exclude data from both of the following:

(A) Health maintenance organizations, as defined in Section 300e(a) of Title 42 of the United States Code, including those organizations that contract under Section 1396b(m) of Title 42 of the United States Code.

(B) Capitated plans that include a prescription drug benefit in the capitated rate, and that have negotiated contracts for rebates or discounts with manufacturers.

(c) In order that Medi-Cal beneficiaries may have access to a comprehensive range of therapeutic agents, the department shall ensure that there is representation on the list of contract drugs in all major therapeutic categories. Except as provided in subdivision (a) of Section 14105.35, the department shall not be required to contract with all manufacturers who negotiate for a contract in a particular category. The department shall ensure that there is sufficient representation of single-source and multiple-source drugs, as appropriate, in each major therapeutic category.

(d) The department shall select the therapeutic categories to be included on the list of contract drugs, and the order in which it seeks contracts for those categories. The department may establish

different contracting schedules for single-source and multiple-source drugs within a given therapeutic category.

(e) (1) In order to fully implement subdivision (d), the department shall, to the extent necessary, negotiate or renegotiate contracts to ensure there are as many single-source drugs within each therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. The department may determine in selected therapeutic categories or subcategories that no single-source drugs are necessary because there are currently sufficient multiple-source drugs in the therapeutic category or subcategory on the list of contract drugs to meet the health needs of the Medi-Cal population. However, in no event shall a beneficiary be denied continued use of a drug which is part of a prescribed therapy in effect as of September 2, 1992, until the prescribed therapy is no longer prescribed.

(2) In the development of decisions by the department on the required number of single-source drugs in a therapeutic category or subcategory, and the relative therapeutic merits of each drug in a therapeutic category or subcategory, the department shall consult with the Medi-Cal Contract Drug Advisory Committee. The committee members shall communicate their comments and recommendations to the department within 30 business days of a request for consultation, and shall disclose any associations with pharmaceutical manufacturers or any remuneration from pharmaceutical manufacturers.

(f) In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(g) In no event shall a beneficiary be denied continued use of a drug that is part of a prescribed therapy in effect as of September 2, 1992, until the prescribed therapy is no longer prescribed.

(h) Contracts executed pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). *Notwithstanding any other provision of law, any contract or amendments to the contract subject to this section shall be open to*

inspection by the chair and vice chair of the following legislative committees, who shall maintain the confidentiality of the contracts and amendments thereto, until the contract or amendments to the contract are open to inspection by the public.

(1) The Assembly Committee on Health.

(2) The Senate Committee on Health and Human Services.

(3) The Assembly Committee on Budget.

(4) The Senate Committee on Budget and Fiscal Review.

(i) The department shall provide individual notice to Medi-Cal beneficiaries at least 60 calendar days prior to the effective date of the deletion or suspension of any drug from the list of contract drugs. The notice shall include a description of the beneficiary's right to a fair hearing and shall encourage the beneficiary to consult a physician to determine if an appropriate substitute medication is available from Medi-Cal.

(j) In carrying out the provisions of this section, the department may contract either directly, or through the fiscal intermediary, for pharmacy consultant staff necessary to initially accomplish the treatment authorization request reviews.

(k) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after the effective date of the act that added this subdivision.

(3) Following final resolution of any dispute pursuant to procedures established by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations regarding the amount of a rebate, any underpayment by a manufacturer shall be paid with interest calculated pursuant to subdivisions (m) and (n), and any overpayment, together with interest at the rate calculated pursuant to subdivisions (m) and (n), shall be credited by the department against future rebates due.

(*l*) Interest pursuant to subdivision (k) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment.

(m) Except as specified in subdivision (n), interest rates and calculations pursuant to subdivision (k) for medicaid rebates and state rebates shall be identical and shall be determined by the federal Centers for Medicare and Medicaid Services' Medicaid Drug Rebate Program Releases or regulations.

(n) If the date of mailing of a state rebate payment is 69 days or more from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer, the interest rate and calculations pursuant to subdivision (k) shall be as specified in subdivision (m), however the interest rate shall be increased by 10 percentage points. This subdivision shall apply to payments for amounts invoiced for any quarters that begin on or after the effective date of the act that added this subdivision.

(o) If the rebate payment is not received, the department shall send overdue notices to the manufacturer at 38, 68, and 98 days after the date of mailing of the invoice, and supporting utilization data. If the department has not received a rebate payment, including interest, within 180 days of the date of mailing of the invoice, including supporting utilization data, the manufacturer's contract with the department shall be deemed to be in default and the contract may be terminated in accordance with the terms of the contract. For all other manufacturers, if the department has not received a rebate payment, including interest, within 180 days of the date of mailing of the invoice, including supporting utilization data, all of the drug products of those manufacturers shall be made available only through prior authorization effective 270 days after the date of mailing of the invoice, including utilization data sent to manufacturers.

(p) If the manufacturer provides payment or evidence of payment to the department at least 40 days prior to the proposed date the drug is to be made available only through prior authorization pursuant to subdivision (o), the department shall terminate its actions to place the manufacturers' drug products on prior authorization.

(q) The department shall direct the state's fiscal intermediary to remove prior authorization requirements imposed pursuant to subdivision (o) and notify providers within 60 days after payment by the manufacturer of the rebate, including interest. If a contract was in place at the time the manufacturers' drugs were placed on prior authorization, removal of prior authorization requirements

shall be contingent upon good faith negotiations and a signed contract with the department.

(r) A beneficiary may obtain drugs placed on prior authorization pursuant to subdivision (o) if the beneficiary qualifies for continuing care status. To be eligible for continuing care status, a beneficiary must be taking the drug when its manufacturer is placed on prior authorization status. Additionally, the department shall have received a claim for the drug with a date of service that is within 100 days prior to the date the manufacturer was placed on prior authorization.

(s) A beneficiary may remain eligible for continuing care status, provided that a claim is submitted for the drug in question at least every 100 days and the date of service of the claim is within 100 days of the date of service of the last claim submitted for the same drug.

(t) Drugs covered pursuant to Sections 14105.43 and 14133.2 shall not be subject to prior authorization pursuant to subdivision (o), and any other drug may be exempted from prior authorization by the department if the director determines that an essential need exists for that drug, and there are no other drugs currently available without prior authorization that meet that need.

(u) It is the intent of the Legislature in enacting subdivisions (k) to (t), inclusive, that the department and manufacturers shall cooperate and make every effort to resolve rebate payment disputes within 90 days of notification by the manufacturer to the department of a dispute in the calculation of rebate payments.

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